

EPA Jacket 2517-178

Part 1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 3, 2020

Prince M. Bamaze
Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Subject: Label Amendment – Update label language
Product Name: Sergeant's Imidacloprid+ Permethrin+ Pyriproxyfen Squeeze On for Dogs
EPA Registration Number: 2517-178
Application Date: December 18, 2019
Decision Number: 558192

Dear Mr. Bamaze:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(c)(7)(A), subject to the following conditions:

1. You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. This registration is time-limited and expires June 15, 2021.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred. (mm/dd/yyyy)
 - State in which the incident occurred. (standard 2 letter abbreviation)

- Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
- All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - A summary table showing the number of dogs incidents for each severity code for each pet weight range on the product label, as applicable.
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
 - Table showing number of incidents for each dog breed, where provided.
 - Table showing number of incidents in dogs for each clinical sign.

- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Vanessa Emerson by phone at 703-347-0360, or via email at emerson.vanessa@epa.gov.

Sincerely,



Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

Sergeant's® Master Label

04 February 2020
Information in { } is note to reviewer.

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EPA Reg. No. 2517-178
Supersedes EPA SAL 6/15/2017

Front Panel

Dogs Squeeze On (Permethrin + Imidacloprid + Pyriproxyfen)

{Text within brackets [] is optional / Text within parenthesis () will appear on the label / Text within braces { } is a note to reviewer}

Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs

{Market Label-the word Dog will be at least 40-75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a dog in the respective weight range will be on the front panel of the label for the product as packaged.}

{One of the following statements will appear prominently on appropriate weight band market label on front panel in a box as required per Agency's pet spot-on mitigation measures:}

For use ONLY on dogs [[&] [and] puppies]] [weighing] [4 -][to] 10 lbs.] [11 -][to] 20 lbs.] [21 -][to] 55 lbs.] [[more than] [over] [>] 55 lbs.] [&] [and] 7 weeks [of age] or older

{The appropriate weight class of dog will correspond to the appropriate applicator size}

{OR}

ONLY for dogs [[&] [and] puppies]] 7 weeks [of age] or older [&] [and] [weighing] [4 -][to] 10 lbs.] [11 -][to] 20 lbs.] [21 -][to] 55 lbs.] [[more than][over][>] 55 lbs.]

{The appropriate weight class of dog will correspond to the appropriate applicator size}

{A minimum of 1.5cm x 1.5cm cat prohibition icon and warning text will be in a box in the lower right hand corner of the front panel with black cat + red circle and line through the cat, black text, on white background to ensure easy spotting.}



{following text will be in addition to the above required language}

Small Dogs 4-10 lbs {only for use on label for 4-10 lbs and 7 weeks or older product}

Medium Dogs 11-20 lbs {only for use on label for 11-20 lbs and 7 weeks or older product}

Large Dogs 21-55 lbs {only for use on label for 21-55 lbs and 7 weeks or older product}

Extra Large Dogs >55 lbs {only for use on label for >55 lbs and 7 weeks or older product}

[Small][Medium][large][Extra Large]

ACTIVE INGREDIENTS:

Imidacloprid.....	8.80%
Permethrin*.....	44.00%
Pyriproxyfen	0.44%

OTHER INGREDIENTS:46.76%

TOTAL100.00%

*cis/trans ratio: Max 55% (+) cis and min 45% (+) trans

ACCEPTED

03/03/2020

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg. No. 2517-178

**KEEP OUT OF REACH OF CHILDREN
WARNING**

See Back Panel for Additional Precautionary Statements

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NET CONTENTS:

{The word "tube", "vial" or "applicator" will be used consistently throughout the label.}

{For Dog Weighing 4-10 lbs.}

1 - 0.014 fl oz (0.4 mL) [tube] [vial] [applicator]
0.028 fl oz (0.8 mL), 2 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.042 fl oz (1.2 mL), 3 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.056 fl oz (1.6 mL), 4 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.070 fl oz (2.0 mL), 5 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.084 fl oz (2.4 mL), 6 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.098 fl oz (2.8 mL), 7 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.112 fl oz (3.2 mL), 8 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.126 fl oz (3.6 mL), 9 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.140 fl oz (4.0 mL), 10 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.154 fl oz (4.4 mL), 11 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.168 fl oz (4.8 mL), 12 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]
0.336 fl oz (9.6 mL), 24 - 0.014 fl oz (0.4 mL) [tubes] [vials] [applicators]

{For Dog Weighing 11-20 lbs.}

1 - 0.034 fl oz (1.0 mL) [tube] [vial] [applicator]
0.068 fl oz (2.0 mL), 2 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.102 fl oz (3.0 mL), 3 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.136 fl oz (4.0 mL), 4 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.170 fl oz (5.0 mL), 5 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.204 fl oz (6.0 mL), 6 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.238 fl oz (7.0 mL), 7 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.272 fl oz (8.0 mL), 8 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.306 fl oz (9.0 mL), 9 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.340 fl oz (10.0 mL), 10 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.374 fl oz (11.0 mL), 11 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.408 fl oz (12.0 mL), 12 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]
0.816 fl oz (24.0 mL), 24 - 0.034 fl oz (1.0 mL) [tubes] [vials] [applicators]

{For Dog Weighing 21-55 lbs.}

1 - 0.085 fl oz (2.5 mL) [tube] [vial] [applicator]
0.170 fl oz (5.0 mL), 2 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
0.255 fl oz (7.5 mL), 3 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
0.340 fl oz (10.0 mL), 4 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
0.425 fl oz (12.5 mL), 5 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
0.510 fl oz (15.0 mL), 6 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
0.595 fl oz (17.5 mL), 7 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
0.680 fl oz (20.0 mL), 8 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
0.765 fl oz (22.5 mL), 9 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
0.850 fl oz (25.0 mL), 10 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
0.935 fl oz (27.5 mL), 11 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
1.020 fl oz (30.0 mL), 12 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]
2.040 fl oz (60.0 mL), 24 - 0.085 fl oz (2.5 mL) [tubes] [vials] [applicators]

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{For Dog Weighing over 55 lbs.}

1 - 0.135 fl oz (4.0 mL) [tube] [vial] [applicator]
0.270 fl oz (8.0 mL), 2 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
0.405 fl oz (12.0 mL), 3 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
0.540 fl oz (16.0 mL), 4 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
0.675 fl oz (20.0 mL), 5 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
0.810 fl oz (24.0 mL), 6 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
0.945 fl oz (28.0 mL), 7 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
1.080 fl oz (32.0 mL), 8 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
1.215 fl oz (36.0 mL), 9 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
1.350 fl oz (40.0 mL), 10 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
1.485 fl oz (44.0 mL), 11 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
1.620 fl oz (48.0 mL), 12 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]
3.240 fl oz (96.0 mL), 24 - 0.135 fl oz (4.0 mL) [tubes] [vials] [applicators]

{Begin Optional Active Ingredient Reference Statements}

[[Brand Name] [This product] contains [the] [same] [the] [active] ingredients [Imidacloprid, pyriproxyfen and permethrin,] used in
[K9 Advantix® II][K9 Advantix® II Small Dog] [K9 Advantix® II Medium Dog] [K9 Advantix® II Large Dog] [K9 Advantix® II Extra Large Dog]]*

[[Brand Name] [This product] contains Imidacloprid, pyriproxyfen and permethrin, the active ingredients used in
[K9 Advantix® II][K9 Advantix® II Small Dog] [K9 Advantix® II Medium Dog] [K9 Advantix® II Large Dog] [K9 Advantix® II Extra Large Dog]]*

{Note to reviewer: Text for footnote statement one}

[*[Brand Name] [This product] is not manufactured or distributed by Bayer Healthcare LLC, the makers of
[K9 Advantix® II][K9 Advantix® II Small Dog] [K9 Advantix® II Medium Dog] [K9 Advantix® II Large Dog] [K9 Advantix® II Extra Large Dog]]

{Note to reviewer: Text for footnote statement two}

***[K9 Advantix® II][K9 Advantix® II Small Dog] [K9 Advantix® II Medium Dog] [K9 Advantix® II Large Dog] [K9 Advantix® II Extra Large Dog]**
is a registered trademark of Bayer Healthcare LLC.]

{End Optional Active Ingredient Reference Statements}

[ABNs]

[AdvanceGuard Ticks2 for Dogs]
[SENTRY® AdvanceGuard Ticks2 for Dogs]
[Advanced Ticks 2 for Dogs]
[PetArmor® Advanced Ticks 2 for Dogs]
[DogMD Maximum Defense™ Advanced Ticks 2 for Dogs]
[DogMD Advanced Ticks 2 for Dogs]
[PetLock Ultra for Dogs]

{END - FRONT PANEL}

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BACK PANEL/SIDE/INSERT PANEL

Dogs Squeeze On
(Permethrin + Imidacloprid + Pyriproxyfen)

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND PUPPIES 7 WEEKS [OF AGE] OR OLDER
AND [WEIGHING] [4-10] [11-20] [21-55] [OVER 55] lbs.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on skin or clothing. Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin. Wash thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. As with any product, consult your veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product. This product is not a substitute for prescribed heartworm preventative.

{Side Effects box to be located immediately above the cat warning box on the back-label panel}

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting, or diarrhea have also been reported. If these or other side effects (such as lethargy or agitation) occur, consult your veterinarian or call 1-800-781-4738.

{A minimum of 1.5cm x 1.5cm cat prohibition icon and warning text will be in a box in the lower right-hand corner of the back panel with black cat + red circle and line through the cat, black text, on white background to ensure easy spotting.}

DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours.
If applied to a cat or ingested by a cat, contact your veterinarian immediately.



ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

FIRST AID	
If In Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RESTRICTIONS:

Do not allow children to apply product
Do not use on animals other than dogs
Do not use on puppies under 7 weeks of age or [weighing] less than [4] [11] [21] [55] lbs
Do not bathe or allow dog to swim for 24 hours after application
Do not get this product in dogs' eyes or mouth
Do not treat with more than one pesticide product at a time
Do not allow your dog to ingest this product
Do not apply more than one [tube] [vial] [applicator] per treatment for one dog regardless of the dog's weight
Do not split [tube] [vial] [applicator] between dogs and, use the entire contents of [tube] [vial] [applicator] on each dog
Dog must be dry at time of application and remain dry for 24 hours after application.
Do not have contact or allow children to have contact with the treated area until completely dry
Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog
Separate treated dogs from one another and other animals to avoid chance of ingestion
Do not reapply for [[four][4] weeks] [30 days] [[1][a] month]

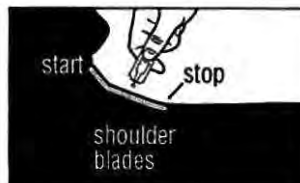
How to Open:

1. Remove product [tube] [vial] [applicator] [s] from the package.
2. Separate one [tube] [vial] [applicator] from the others. Hold the [tube] [vial] [applicator] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert [tube] [vial] [applicator] over dog and use open end to part dog's hair.
2. Squeeze [tube] [vial] [applicator] firmly to apply all of the solution to the dog's skin [as a spot to the dog's back between the shoulder blades] {or} [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail.]

{How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling. Refer to following optional graphics.}



FREQUENCY OF APPLICATION

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].] [[Studies show that] [Brand Name {or} This product] kills fleas within 12 hours of application and [lasts {or} protects for [[four][4] weeks] [30 days] [[1][a] month].]
[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours][two hours] and prevents further infestations of fleas for [[four][4] weeks] [30 days] [1][a] month].]
[[Brand Name {or} This product] [targets multiple flea life stages] [and] [kills flea eggs and larvae before

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they develop into biting adults.].

[[Brand Name {or} This product] breaks the flea life cycle by killing flea eggs, flea larvae, and adult fleas.]

[Apply monthly for flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after bathing, swimming, or exposure to sunlight [and][or] [rain].] [Allow treated area to dry thoroughly before touching.]

[PRODUCT INFORMATION]

[The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with [Brand Name] [this product] kills fleas that may be a source of FAD.]

[[Brand Name] [This product] kills existing fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting [[four] [4] weeks.] [[1][a] month] [30 days].

[Brand Name] [This product] is waterproof and remains effective following a shampoo bath, swimming or after exposure to rain or sunlight.]

[Monthly treatments are required for optimal control and prevention of fleas and ticks.]

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: store in a cool, dry place. Protect from freezing.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. **If empty:** Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY]

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's, Inc.] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

[Satisfaction Guaranteed. If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-781-4738
Non-Emergency, call: 1-800-224-PETS (7387)

[Made in USA With Global Materials]
[Patent Number: 10172359]

[Coupon(s) inside or on outside of box]

{Note to reviewer: When outside the box, coupon will not cover or distract consumer from required text.}

[Distributed by:] [Manufactured by:]
Sergeant's Pet Care Products, Inc.
Omaha, NE 68138-3710

EPA Reg. No. 2517-178
EPA Est. No. XXXXX-XX-XX
[BAR CODE AREA]

{END - BACK/SIDE PANEL}

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{START – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

Clip. Part. Squeeze.

Easier-than-ever applicator lets you **clip** the tip, **part** the fur and **apply** directly to the skin – putting protection from fleas where it needs to be.

Application Instructions

How to Open:

1. Remove product [tube] [vial] [applicator] [s] from the package.
2. Separate one [tube] [vial] [applicator] from the others. Hold the [tube] [vial] [applicator] with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

How to Apply:

1. Invert [tube] [vial] [applicator] over dog and use open end to part dog's hair.
2. Squeeze [tube] [vial] [applicator] firmly to apply all of the solution to the dog's skin [as a spot to the dog's back between the shoulder blades] {or} [as a [stripe] [line] starting from the back of the neck to a point midway between the neck and tail.]

[Brand Name] [This product]

[Monthly reminder card]

[1][2][3][4][5][6] [12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year-round protection, apply [Brand Name][this product] monthly.]

[Dog's Name (Empty blank for owner to fill in name)]

[Dog's Weight (Empty blank for owner to fill in name)]

[First][1st][Second][2nd][Third][3rd][Fourth][4th][Fifth][5th][Sixth][6th][Seventh][7th][Eighth]

[8th][Ninth][9th][Tenth][10th][Eleventh][11th][Twelfth][12th]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)

[Application Date][Date of Application]

[Calendar stickers with Brand Name]









[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] [in 30 days.]

[Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your dog]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

{Each optional graphic below may or may not appear anywhere on the finished label}

	Adult Flea	
	Fleas	
	Flea Eggs	
	Flea Larvae	

Sergeant's® Master Label

04 February 2020

















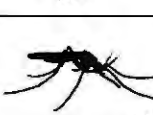


Information in { } is note to reviewer.

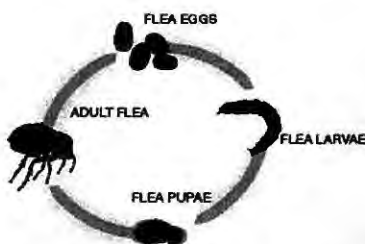
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	Ticks	
	Deer Ticks	
	Brown Dog Ticks	
	Lone Star Ticks	
	American Dog Ticks	
	Lice	
	Biting Lice	
	Chewing Lice	
	Mosquitoes	
	Biting Flies	



[Flea life cycle diagram] [Flea Life Cycle]

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***Refund or replacement of product {text footnote to satisfaction guaranteed graphic}**

{END – ADDITIONAL OPTIONAL PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT}

TUBE/VIAL LABEL

**Dogs Squeeze On
(Imidacloprid + Pyriproxyfen + Permethrin)**

{Front Label}	{Back Label}
Brand Name {for dogs} [4-10][11-20][21-55][>55] lbs. ≥7 wks Imidacloprid 8.8%, Permethrin 44%, Pyriproxyfen 0.44% 0.014 fl oz {or} 0.034 fl oz {or} 0.085 fl oz {or} 0.135 fl oz {label code}	KEEP OUT OF REACH OF CHILDREN WARNING Read directions and precautions on package. Use scissors to open. EPA REG. No. 2517-178 {label code}



{Lot No. is engraved on the crimp portion of the tube} {EPA REG No may be on either the front or back label}

{Label code refers to Sergeant's product code number assignment to each product}

{END – TUBE/VIAL LABEL}

{Optional marketing statements below may or may not appear anywhere on the finished label}

Flea/Flies Marketing Claims

- {1} Kills fleas
- {2} Repels and kills Fleas
- {3} Kills fleas on dogs
- {4} Active against fleas
- {5} Treats Fleas
- {6} Prevents Fleas
- {7} Repels biting flies
- {8} Controls against [irritating] flea bites
- {9} [Brand Name] [this product] Offers protection against fleas
- {10} Prevents and treats flea[s] [infestations]
- {11} Controls existing infestations by killing adult fleas
- {12} Controls existing flea infestation by killing adult fleas
- {13} Repels and kills fleas before they lay eggs
- {14} For the prevention and treatment of Flea Infestations
- {15} Prevents reinfestations by killing adult fleas before they lay eggs
- {16} Kills fleas even if your dog gets wet
- {17} Use monthly for control of fleas
- {18} Controls fleas, which can serve as an intermediate tapeworm host
- {19} Repels, and [inhibits] [prevents] blood-feeding by biting flies
- {20} [prevents] [inhibits] blood-feeding by biting flies
- {21} Repels [annoying] [bothersome] [nuisance] biting flies
- {22} Inhibits [annoying] [bothersome] [nuisance] biting flies
- {23} Kills reinfesting fleas within 2 hours [and protects against further infestation]
- {24} Kills fleas within 12 hours [of application] [on dogs]
- {25} Kills fleas within 12 hours, continues to kill for 4 weeks
- {26} Kills fleas on dogs within 12 hours and continues to prevent infestations for [[1][a] month] [[four] [4] weeks] [30 days]

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- {27} Kills fleas within 12 hours on dogs [and prevents further infestations for [[4][four] weeks] [[1][a] month] [30 days]
- {28} One treatment prevents further flea infestations for [[1][a] month] [[four] [4] weeks] [30 days]
- {29} Prevents further flea infestation for [[four][4] weeks] [[1] [a] month] [30 days] with one [treatment] [application].
- {30} [Brand Name] [this product] Prevents further flea infestation for [[four][4] weeks] [[1][a] month] [30 days]
- {31} Once per month topical flea treatment for dogs
- {32} Once-a-month topical treatment for fleas on dogs
- {33} Prevents flea reinfestations for [30 days] [[1][a] month] [[four][4] weeks]
- {34} Prevents further flea infestations on dogs for [30 days] [[1][a] month] [[four][4] weeks]
- {35} Apply monthly [for effective flea control]
- {36} Apply monthly [to control and prevent fleas]
- {37} Monthly topical flea treatment for dogs
- {38} Monthly treatments are required for optimal control and prevention of fleas
- {39} The Protection From Fleas You Need For Your Dog [s] When Applied Monthly!
- {40} [Once per month] [Monthly] topical flea treatment for dogs 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] [lbs] [pounds] {weight range depends upon appropriate ml/fl oz package size}
- {41} Once-a-month topical treatment for fleas on dogs 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] [lbs] [pounds] {weight range depends upon appropriate ml/fl oz package size}
- {42} Kills fleas on dogs and puppies 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] [pounds] [lbs] {weight range depends upon appropriate ml/fl oz package size}
- {43} [Brand Name] [This product] is for the treatment and prevention of fleas on dogs
- {44} Flea control for puppies and dogs 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] [lbs][pounds] {weight range depends upon appropriate ml/fl oz package size}
- {45} Flea control for puppies and dog 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] [lbs][pounds]] {weight range depends upon appropriate ml/fl oz package size}
- {46} [Brand Name] [This product] is for the treatment and prevention of fleas on dogs 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] [lbs][pounds] {weight range depends upon appropriate ml/fl oz package size}
- {47} Kills fleas, which may be a source of flea allergy dermatitis within 12 hours
- {48} Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation
- {49} Use of [Brand Name] [this product] kills fleas that may cause flea bite hypersensitivity [and] [or] [flea allergy dermatitis] [FAD]
- {50} Monthly treatment with [Brand Name] [this product] kills fleas that may cause [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]
- {51} Monthly treatment with [Brand Name] [this product] kills fleas that may cause flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]
- {52} Treatment with [Brand Name] [this product] kills fleas that may cause Flea Allergic Dermatitis [FAD]
- {53} [Brand Name] [This product] kills fleas that may cause a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on dogs.]

Ticks Marketing Claims

- {54} Kills Ticks
- {55} Treats Ticks
- {56} Prevents Ticks
- {59} Repels and kills Ticks
- {60} Repels and kills ticks including Deer ticks (vector of Lyme disease), American dog ticks (vector of Rocky Mountain spotted fever), Brown dog ticks (vector of Ehrlichiosis), and Lone Star ticks (vector of Ehrlichiosis), for four weeks

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Mosquitoes Marketing Claims

- {61} Repels and kills Mosquitos
- {62} Repels and kills mosquitoes [for four weeks]
- {63} Repels and kills mosquitoes often before they have a chance to take a blood meal
- {64} Reduces blood-feeding by mosquitoes
- {65} Kills and repels mosquitoes

Lice Marketing Claims

- {66} Kills Lice
- {67} Kills [biting] [chewing] lice
- {68} Controls existing [biting] [chewing] lice infestations
- {69} Kills [biting] [chewing] lice and prevents further infestations
- {70} Provides effective control of [biting] [chewing] lice [infestations]
- {71} Treats, prevents and controls [biting] [chewing] lice [infestations]
- {72} For treatment and prevention of [biting] [chewing] lice [infestations]
- {73} For treatment and prevention of infestations with [biting] [chewing] lice

IGR Marketing Claims

- {74} Kills flea eggs
- {75} Controls existing flea eggs
- {76} Prevents flea eggs from hatching
- {77} Prevents flea eggs from developing into [biting] adult fleas
- {78} Prevents the development of flea eggs into [biting] adult fleas
- {79} [Brand Name] [This product] contains Pyriproxyfen [PPF] [an insect growth regulator (IGR)] to kill flea eggs [and protect against reinfestation]
- {80} Prevents flea eggs [and flea larvae] from developing into [biting] adult fleas
- {81} Prevents development of fleas, flea eggs, pupae and larvae for [[1] [a] month] [[four] [4] weeks] [30days]
- {82} Kills [flea eggs and] flea larvae
- {83} Kills flea eggs and flea larvae for [[four] [4] weeks] [[1][a] month] [30 days]
- {84} Controls existing flea eggs and fleas and prevents future infestations for [[four] [4] weeks] [[1][a] month] [30 days]
- {85} Monthly treatment controls existing flea eggs and fleas and prevents future infestations
- {86} Kills multi-stages of fleas
- {87} Kills multiple flea life stages
- {88} Breaks the flea life cycle
- {89} Effectively breaks the flea life cycle
- {90} Targets multi-stages of flea lifecycle
- {91} Controls multi-stages of flea lifecycle
- {92} Repels and kills all [life] stages of fleas
- {93} Prevents development of all flea stages [for [1][a] month] [[four] [4] weeks] [30 days]
- {94} Provides multi-stage flea control
- {95} Prevents multi-stages of the flea life cycle from developing
- {96} Effectively targets all [life] stages of flea
- {97} Effectively targets all [life] stages of ticks
- {98} [Brand Name] [this product] contains [an][the] [insect growth regulator] [IGR] [, Pyriproxyfen], in addition to Imidacloprid, and permethrin
- {99} [Brand Name] [this product] contains [Imidacloprid], [permethrin] and [an/the] [insect growth regulator] [IGR] [Pyriproxyfen]

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COMBO Marketing Claims

- {100} Kills fleas before eggs can be laid
- {101} Treats ticks, fleas [and mosquitoes]
- {102} Prevents ticks, fleas [and mosquitoes]
- {103} Repels and kills ticks, fleas [and mosquitoes]
- {104} Flea Adulticide, larvicide and ovicide
- {105} [Brand Name] [This product] is a flea ovicide, larvicide, and adulticide
- {106} Kills flea eggs, larvae, and [adult] fleas
- {107} Kills [adult] fleas, flea eggs, and flea larvae
- {108} Kills [adult] fleas, flea eggs and flea larvae for [[four] [4] weeks] [[1][a] month] [30 days]
- {109} Kills [adult] fleas, larvae, and eggs [, providing three-way protection]
- {110} 3-way protection from fleas [!] Kills adults, larvae and eggs
- {111} 3-way protection from fleas [!] [Kills] [controls] adults, larvae, and eggs
- {112} 5-way protection against fleas, ticks, biting flies, mosquitoes, and lice
- {113} Topical prevention and treatment of ticks, fleas, mosquitoes, biting flies, and lice for monthly use
- {114} [Brand Name] [This product is indicated for the prevention and treatment of fleas, ticks, biting flies, mosquitoes, and lice on dogs 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] [lbs][pounds]

All Other Marketing Claims

- {115} [Begins] [Starts] working through contact
- {116} For use on dogs and puppies 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] [lbs][pounds]
- {117} Apply to dogs [and puppies] 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}
- {118} Formulated for Dogs and Puppies 7 Weeks [of Age] or older and [4-10] [11-20] [21-55] [over 55] lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}
- {119} Dogs and Puppies 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}
- {120} Can be used on puppies 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}
- {121} Convenient
- {122} Easy application
- {123} Easy to apply product
- {124} Easy to Use [Application]
- {125} One Step Hassle Free Protection!
- {126} Convenient, easy to apply topical solution
- {127} Fragrance free
- {128} Waterproof
- {129} Remains effective even after the dog swims
- {130} Remains effective after bathing and/or swimming
- {131} Remains effective following swimming and/or shampooing
- {132} Remains effective after exposure to rain or sunlight
- {133} Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to [sunlight [and][or] rain]
- {134} Once a month treatment
- {135} Apply once every [[four] [4] weeks] [[1] month]] [30 days] [!]
- {136} [[four][4] Week] [[1] Month] [30 Day] Dose [!]
- {137} Once a month topical flea treatment for dogs 7 weeks [of age] or older and [4-10] [11-20] [21-55] [over 55] [lbs][pounds]

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{138} A single topical application remains effective for [[1][a] month] [[four] [4] weeks] [30 days]

One [tube] [vials] [applicators]	[1 Month Supply]
Two [tube] [vials] [applicators] pack	[2 Month Supply]
Three [tube] [vials] [applicators] pack	[3 Month Supply]
Four [tube] [vials] [applicators] pack	[4 Month Supply]
Five [tube] [vials] [applicators] pack	[5 Month Supply]
Six [tube] [vials] [applicators] pack	[6 Month Supply]
9 [tube] [vials] [applicators] pack	[9 Month Supply]
12 [tube] [vials] [applicators] pack	[12 Month Supply]
24 [tube] [vials] [applicators] pack	[24 Month Supply]
Direct to skin [tube] [vial] [applicator]	
Easy to Use [tube] [vial] [applicator]	
No-mess [open] [tube] [vial] [applicator]	
Clip-tip design [tube] [vial] [applicator] [!]	

{Consumer Value Marketing Claims}

{Note to Reviewer: Buying a larger pack reduces the price, therefore the cost effective without the addition of extra applicators; Combinations of "x" and "y" will correspond to the Net Contents; All applicators will be included inside the carton.}

[Coupon Inside]	[Sample size]
[Save Now!]	[Sample-Not for (re)sale]
[Value Size]	[Buy more and save!]
[Value pack]	[Buy X Get Y Free]
[Club Size]	[Buy 3[4] get 1 free]
[Bonus Size]	[(x)% (More) (Free)!]
[Club Pack]	[25 [33]% more free]
[Great Value]	[(x) Dose(s) Free!]
[Better Value]	[(x) Month(s) Free!]
[Bonus Pack]	[(x) Tube(s) Free!]
[Bonus Buy]	[(x) Applicator(s) Free!]
[[1][2][4][6][7][8][9][X] pack]	[(x) Application(s) Free!]
[Twin Pack]	[33% More Free]
[Try Now, Save Later!]	
[Z% Free]	
[(x) + (x) bonus pack!]	
[free sample]	

[Topical prevention and treatment of ticks, fleas, mosquitoes, biting flies, and lice for monthly use.] [For the prevention and treatment of ticks, fleas, mosquitoes, biting flies, and lice on dogs.]

[The active ingredients in [Brand name][this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas [and flea eggs] on dogs.] [[Brand Name] [This product] kills fleas within 12 hours and prevents further flea infestations for [[4][four]weeks] [[1][one] month] [30 days].]

Emerson, Vanessa

From: Emerson, Vanessa
Sent: Monday, March 2, 2020 2:03 PM
To: Emerson, Vanessa
Subject: RE: Status of GDCIs for permethrin

From: Emerson, Vanessa <emerson.vanessa@epa.gov>
Sent: Tuesday, December 10, 2019 8:27 AM
To: Pinto, Ana <Pinto.Ana@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: RE: Status of GDCIs for permethrin

Thank you, Ana!

From: Pinto, Ana <Pinto.Ana@epa.gov>
Sent: Tuesday, December 10, 2019 8:26 AM
To: Emerson, Vanessa <emerson.vanessa@epa.gov>
Cc: Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: RE: Status of GDCIs for permethrin

Hi Vanessa,

My name's Ana, I'm the new CRM that's been assigned to permethrin. All of the DCIs for permethrin have been satisfied.

Thanks,

Ana Pinto
Chemical Review Manager, Risk Management and Implementation Branch III (RMIB III)
Pesticide Re-Evaluation Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-8421
Pinto.Ana@epa.gov

From: Emerson, Vanessa <emerson.vanessa@epa.gov>
Sent: Friday, December 06, 2019 4:38 PM
To: Sell, Nathan <Sell.Nathan@epa.gov>; Jakob, Avivah <Jakob.Avivah@epa.gov>
Subject: Status of GDCIs for permethrin

Hi Nathan and Avivah,

We're about to register a new product containing Permethrin. I looked up the GDCIs in PRISM and see the following listed as active. Is this information correct or have the DCIs been satisfied? We need this information in order to determine if the registration should be conditional or unconditional.

Permethrin:

<u>GDCI-109701-1113</u>	DCI GDCI-109701-1113 for Company: BAYER ENVIRONMENTAL SCIENCE
<u>GDCI-109701-1252</u>	DCI GDCI-109701-1252 for Company: MCLAUGHLIN GORMLEY KING CO

Thank you for your help,
Vanessa

Vanessa Emerson | Physical Scientist | Invertebrate and Vertebrate Branch 1

Registration Division | Office of Pesticide Programs | Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency: 1200 Pennsylvania Avenue NW, 7505-P, Washington, D.C. 20460

☎ Phone: (703) 347-0360 | ✉ emerson.vanessa@epa.gov | Office: PY-S7213

Emerson, Vanessa

From: Fothergill, Kent
Sent: Monday, March 2, 2020 2:23 PM
To: Emerson, Vanessa
Cc: Godshall, Joshua; Grable, Melissa
Subject: RE: Status of GDCIs for Pyriproxyfen
Attachments: pyriproxyfen ID_09_16_19_Signed.pdf

Dear Vanessa

The ID for pyriproxyfen was signed Sept of 2019. Melissa Grable is no longer the TL for this chemical, she has been replaced with Josh Godshall. With regard to data requirements here is an ID excerpt from page 15:

D. Data Requirements

The EPA anticipates requiring the pyriproxyfen registrants to submit as a separate action.

Between the PID and ID a pet collar torsion study was submitted that cleared up a lot of uncertainty. Based on the PID and ID I would say there are no outstanding DCI requirements. GDCI-129032-1299 is from 2013. Please let me know if you require further information.

P&L

Kent

From: Emerson, Vanessa <emerson.vanessa@epa.gov>
Sent: Monday, March 2, 2020 1:59 PM
To: Fothergill, Kent <fothergill.kent@epa.gov>; Grable, Melissa <Grable.Melissa@epa.gov>
Cc: Fertich, Elizabeth <fertich.elizabeth@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: Status of GDCIs for Pyriproxyfen

Hi Kent and Melissa,

We're about to register a new product containing pyriproxyfen. I looked up the GDCIs in PRISM and see the following listed as active. Is this information correct or have the DCIs been satisfied? We need this information in order to determine if the registration should be conditional or unconditional.

Pyriproxyfen:

GDCI-129032-1299

DCI GDCI-129032-1299 for Company: RAYMAT MATERIALS INC.

DCI/Order

Thank you for your help,
Vanessa

Vanessa Emerson | Physical Scientist | Invertebrate and Vertebrate Branch 1
Registration Division | Office of Pesticide Programs | Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency: 1200 Pennsylvania Avenue NW, 7505-P, Washington, D.C. 20460
☎ Phone: (703) 347-0360 | ✉ emerson.vanessa@epa.gov | Office: PY-S7213

Emerson, Vanessa

From: Snyderman, Steven
Sent: Monday, March 2, 2020 2:04 PM
To: Emerson, Vanessa; Jones, RDavid
Cc: Fertich, Elizabeth; IVB1
Subject: RE: Status of GDCIs for imidacloprid

Follow Up Flag: Follow up
Flag Status: Flagged

The Proposed Interim Decision for imidacloprid is out and all data requirements have been satisfied.

Steven Snyderman, Acting Product Manager
Antimicrobials Division, Team 33
Office of Pesticide Programs
Environmental Protection Agency
Snyderman.Steven@epa.gov
(703) 347-0249

From: Emerson, Vanessa <emerson.vanessa@epa.gov>
Sent: Monday, March 02, 2020 1:56 PM
To: Snyderman, Steven <Snyderman.Steven@epa.gov>; Jones, RDavid <Jones.Rdavid@epa.gov>
Cc: Fertich, Elizabeth <fertich.elizabeth@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: Status of GDCIs for imidacloprid

Hi Steven and David,

We're about to register a new product containing imidacloprid. I looked up the GDCIs in PRISM and see the following listed as active. Is this information correct or have the DCIs been satisfied? We need this information in order to determine if the registration should be conditional or unconditional.

Imidacloprid:

<u>GDCI-129099-1516</u>	DCI GDCI-129099-1516 for Company: WILLOWOOD IMIDACLOPRID, LLC	DCI/Order
<u>GDCI-129099-951</u>	DCI GDCI-129099-951 for Company: SOURCE DYNAMICS, LLC	DCI/Order

Thank you for your help,
Vanessa

Vanessa Emerson | Physical Scientist | Invertebrate and Vertebrate Branch 1
Registration Division | Office of Pesticide Programs | Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency: 1200 Pennsylvania Avenue NW, 7505-P, Washington, D.C. 20460
☎ Phone: (703) 347-0360 | ✉ emerson.vanessa@epa.gov | Office: PY-S7213



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 2, 2020

Prince M. Bamaze
Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Subject: Notification per PRN 98-10 – Addition of alternate brand name
Product Name: Sergeant's Imidacloprid+ Permethrin+ Pyriproxyfen Squeeze On for Dogs
EPA Registration Number: 2517-178
Application Date: December 11, 2019
Decision Number: 559400

Dear Mr. Bamaze:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name "PetLock Ultra for Dogs" has been added to the product record.

If you have any questions, please contact Vanessa Emerson at 703-347-0360 or by email at emerson.vanessa@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Fertich".

Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

December 11, 2019

Jacquelyn Herrick, PM 3
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Subject: **Notification for new Alternate Brand Name per PR Notice 98-10.**

Dear Ms. Herrick,

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is hereby submitting an application for notification, to add alternate brand names to the EPA Registration Numbers indicated below. In support of this action, please find enclosed the EPA Applications Form 8570-1.

- **EPA Reg. No. 2517-175, Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats**

*Proposed Alternate Brand Name: **PetLock for Cats***

- **EPA Reg. No. 2517-178, Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs**

*Proposed Alternate Brand Name: **PetLock Ultra for Dogs***

This Notification is consistent with provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and, no other changes have been made to the labeling or the confidential statement of formula of these products. I understand that it is a violation of 18 U.S.C Sec.1001 to willfully make a false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Should you have any questions regarding this submission, please contact me at 402-938-7065 or by email at prince.bamaze@Petiq.com

Sincerely,

Prince M Bamaze

Prince M. Bamaze

Regulatory Affairs,
Sergeant's Pet Care Products, Inc.
A PetIQ, Inc. Company

Enclosures

DOCUMENTUM

EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 2517-178		2. EPA Product Manager Jacquelyn Herrick	
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Submission in response to Agency letter dated XX-XX-XX <input checked="" type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.)			
Notification for Alternate Brand Name per PR notice 98-10. Please see cover letter for details.			
Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.014 fl oz (0.4 ml) 0.034 fl oz (1.0 ml) 0.085 fl oz (2.5 ml) 0.135 fl oz (4.0 ml)	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. _____	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Prince M. Bamaze		Title Regulatory Affairs	Telephone No. (include Area Code) 402 938-7065
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) <div style="font-size: 2em; font-weight: bold; transform: rotate(-15deg);">DOCUMENTUM</div>
2. Signature BY: <i>Prince M Bamaze</i>		3. Title: Regulatory Affairs, Sergeant's pet Care Products, Inc.	
4. Typed Name: Prince M. Bamaze		5. Date: 12/11/2019	

Emerson, Vanessa

From: Prince Bamaze <Prince.Bamaze@petiq.com>
Sent: Thursday, February 6, 2020 4:04 PM
To: Emerson, Vanessa
Cc: Fertich, Elizabeth; Kelly Hoskins; IVB1
Subject: RE: 2517-178 - label comments
Attachments: 2517-178 V20.1 ML AMND Clean 06Feb20.pdf

Hi Vanessa,

Attached is the revised label. The restriction statement below has been added as requested:
Do not reapply for [[four][4] weeks] [30 days] [[1][a] month]

Thank you,

Prince Bamaze | Regulatory Affairs Associate

10077 S. 134th Street | Omaha, NE 68138-3710
T: (402) 938-7065
E: prince.bamaze@petiq.com



From: Emerson, Vanessa <emerson.vanessa@epa.gov>
Sent: Thursday, February 6, 2020 1:56 PM
To: Prince Bamaze <Prince.Bamaze@petiq.com>
Cc: Fertich, Elizabeth <fertich.elizabeth@epa.gov>; Kelly Hoskins <Kelly.Hoskins@petiq.com>; IVB1 <IVB1@epa.gov>
Subject: RE: 2517-178 - label comments

Hi Prince,

Please find label comments attached.

Thank you,
Vanessa

From: Prince Bamaze <Prince.Bamaze@petiq.com>
Sent: Tuesday, February 4, 2020 4:45 PM
To: Emerson, Vanessa <emerson.vanessa@epa.gov>; Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Cc: Kelly Hoskins <Kelly.Hoskins@petiq.com>; IVB1 <IVB1@epa.gov>; Prince Bamaze <Prince.Bamaze@petiq.com>
Subject: RE: 2517-178 - label comments

Hi Vanessa,

Please find attached the marked and clean copies of the revised label. Based on Beth's email confirming that the application for ABN notification dated 12/11/2019 is in your queue, I took the opportunity of this revision to add the ABN 'PetLock Ultra for Dogs' to the label.

I figured combining the two actions at this point will save the Agency processing time, unless it is easier for you to process the application for ABN notification first and separately. I look forward to a quick final approval of this registration label. Please let me know if anything else is needed.

Best regards,

Prince Bamaze | Regulatory Affairs Associate

10077 S. 134th Street | Omaha, NE 68138-3710

T: (402) 938-7065

E: prince.bamaze@petiq.com



From: Emerson, Vanessa <emerson.vanessa@epa.gov>

Sent: Monday, January 27, 2020 9:17 AM

To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>; Prince Bamaze <Prince.Bamaze@petiq.com>

Cc: Kelly Hoskins <Kelly.Hoskins@petiq.com>; IVB1 <IVB1@epa.gov>

Subject: 2517-178 - label comments

Hi Prince,

Please find label comments attached. Please let me know if you have any questions.

Thanks,
Vanessa

From: Fertich, Elizabeth <fertich.elizabeth@epa.gov>

Sent: Thursday, December 19, 2019 11:55 AM

To: Prince Bamaze <Prince.Bamaze@petiq.com>; Emerson, Vanessa <emerson.vanessa@epa.gov>

Cc: Kelly Hoskins <Kelly.Hoskins@petiq.com>; IVB1 <IVB1@epa.gov>

Subject: RE: EPA Registration Status for Reg. No. 2517-178

Prince,

Please see the attached letter. The new expiration date is reflected in our database and the letter will be uploaded to PPLS in the next day or so. Vanessa will contact you regarding the revised labels you submitted.

Kind regards,
Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
fertich.elizabeth@epa.gov
703-347-8560

From: Fertich, Elizabeth
Sent: Wednesday, December 18, 2019 1:42 PM
To: Prince Bamaze <Prince.Bamaze@petiq.com>; Emerson, Vanessa <emerson.vanessa@epa.gov>
Cc: Kelly Hoskins <Kelly.Hoskins@petiq.com>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA Registration Status for Reg. No. 2517-178

Thanks, Prince. I entered the label amendment in our tracking system. You should have received the milestone 1 email. Vanessa and I will work on the extension letter today.

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
fertich.elizabeth@epa.gov
703-347-8560

From: Prince Bamaze <Prince.Bamaze@petiq.com>
Sent: Wednesday, December 18, 2019 12:13 PM
To: Emerson, Vanessa <emerson.vanessa@epa.gov>
Cc: Kelly Hoskins <Kelly.Hoskins@petiq.com>; Fertich, Elizabeth <fertich.elizabeth@epa.gov>; IVB1 <IVB1@epa.gov>; Prince Bamaze <Prince.Bamaze@petiq.com>
Subject: RE: EPA Registration Status for Reg. No. 2517-178

Hi Vanessa,

Attached is the Application (EPA Form 8570-1) for label amendment you requested. I have also attached the marked and clean copies of the revised registration label. Nearly all your comments have been addressed. As you indicated below, I look forward to the registration extension being granted immediately, while the revised label is being processed. Please let me know if you need anything else.

Best regard,

Prince Bamaze | Regulatory Affairs Associate

10077 S. 134th Street | Omaha, NE 68138-3710
T: (402) 938-7065
E: prince.bamaze@petiq.com



From: Emerson, Vanessa <emerson.vanessa@epa.gov>
Sent: Wednesday, December 11, 2019 1:17 PM
To: Prince Bamaze <Prince.Bamaze@petiq.com>
Cc: Kelly Hoskins <Kelly.Hoskins@petiq.com>; Fertich, Elizabeth <fertich.elizabeth@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: EPA Registration Status for Reg. No. 2517-178

Hi Prince,

Thank you for your patience. When granting a spot-on extension, the following information is verified:

1. The reviewer will look at the most recent label approved on PPLS and verify that all of the required mitigation is included and accurate.
2. The reviewer will verify that there is only one formulation. You can have alternate CSFs with additional sources of active ingredient, however you may only have one formulation.
3. Finally, the reviewer will check our system to verify that enhanced reporting is being submitted.

For 2517-178, the label review indicated that some of the required mitigation is missing or inaccurate. Please see the attached label comments. In order to grant the extension, please send us an application form for a label amendment and indicate a timeframe for responding. Since this review may take a fair amount of time, we will go ahead and grant the extension and post that letter onto PPLS. Afterwards, we will continue with our review of the label. Once completed, the acceptance letter and stamped label will be posted onto PPLS.

Kindly,
Vanessa

From: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Sent: Friday, December 6, 2019 8:05 PM
To: Prince Bamaze <Prince.Bamaze@petiq.com>
Cc: Kelly Hoskins <Kelly.Hoskins@petiq.com>; Emerson, Vanessa <emerson.vanessa@epa.gov>
Subject: Re: EPA Registration Status for Reg. No. 2517-178

Hi Prince,
Vanessa and I have been working on some label comments and will finalize the comments Monday.
Beth

On Dec 6, 2019, at 5:04 PM, Prince Bamaze <Prince.Bamaze@petiq.com> wrote:

Hi Beth,

Would you provide the current status of the Application for registration extension regarding the subject line registration?

We were expecting to hear from you this week.

Best regards,

Prince Bamaze | Regulatory Affairs Associate

10077 S. 134th Street | Omaha, NE 68138-3710
T: (402) 938-7065
E: prince.bamaze@petiq.com
<image001.png>

From: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Sent: Tuesday, November 26, 2019 10:33 AM
To: Prince Bamaze <Prince.Bamaze@petiq.com>

Cc: Kelly Hoskins <Kelly.Hoskins@petiq.com>; Emerson, Vanessa <emerson.vanessa@epa.gov>

Subject: RE: EPA Registration Status for Reg. No. 2517-178

Hi Prince,

The extension is assigned to Vanessa Emerson. She is out of the office this week for the holiday, but I will work with her next week to complete the action. Thanks for providing the letter from NYS. I apologize for the significant delay on many of these extensions.

Kind regards,

Beth

Elizabeth Fertich

US Environmental Protection Agency

Office of Pesticide Programs

Registration Division (7505P)

Invertebrate and Vertebrate Branch 1 (IVB1)

Product Manager 4

fertich.elizabeth@epa.gov

703-347-8560

From: Prince Bamaze <Prince.Bamaze@petiq.com>

Sent: Tuesday, November 26, 2019 10:49 AM

To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>

Cc: Kelly Hoskins <Kelly.Hoskins@petiq.com>; Prince Bamaze <Prince.Bamaze@petiq.com>

Subject: EPA Registration Status for Reg. No. 2517-178

Importance: High

Good morning Beth,

Sergeant's Pet Care Products, Inc. submitted applications for registration extension on 03/15/2019 (see attached submission letter), for EPA Reg. Nos. 2517-145, 2517-147, 2517-148 and 2517-178. The registration extensions have been granted for all registrations listed except for EPA Reg. No. 2517-178. This registration has technically expired on 06/15/2019 as pointed out by the state of New York (See the attached email).

The EPA evidence of product registration is needed ASAP to complete the registration process in NY and elsewhere.

Would you please provide the registration extension letter for this product at your earliest convenience, or let me know what else is needed to process the application for registration extension for this product.

Best regards,

Prince Bamaze | Regulatory Affairs Associate

10077 S. 134th Street | Omaha, NE 68138-3710

T: (402) 938-7065

E: prince.bamaze@petiq.com

<image001.png>

EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 2517-178		2. EPA Product Manager Elizabeth Fertich	
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section II			
<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Submission in response to Agency letter dated XX-XX-XX <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.)			
Registration label amendment to address required mitigation measures for pet spot-on products.			
Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container 0.014 fl oz (0.4 ml) 1,2,3,4,5,6, 0.034 fl oz (1.0 ml) 12,24 vials 0.085 fl oz (2.5 ml) 0.135 fl oz (4.0 ml)	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per Container _____ _____	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Prince M. Bamaze		Title Regulatory Affairs	
		Telephone No. (Include Area Code) 402 938-7065	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature BY: <i>Prince M Bamaze</i>		3. Title: Regulatory Affairs, Sergeant's pet Care Products, Inc.	
4. Typed Name: Prince M. Bamaze		5. Date: 12/18/2019	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 19, 2019

Mr. Prince M. Bamaze
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138

Subject: Notice of Extension of Conditional Registration until June 15, 2021

Dear Mr. Bamaze:

This letter is in reference to your request dated March 15, 2019 to extend the following conditional time-limited registration:

Sergeant's Imidacloprid+ Permethrin+ Pyriproxyfen Squeeze On for Dogs EPA Reg. No. 2517-178

The above-referenced registration contains conditions calling for the registration to expire two years from the date in the registration notice dated June 15, 2017. The terms of this registration has been previously updated to extend the expiration date to June 15, 2019. Additionally, your company is required to adhere to the spot-on label mitigation, submit quarterly enhanced incident reports and quarterly sales information for the above registration.

The Agency has found Sergeant's Pet Care Products, Inc. in compliance with the terms and conditions for the subject product. Therefore, the following change is being made to the terms and conditions of the product listed above:

- **The 2-year time-limited registration restriction has been extended an additional two (2) years. Therefore, the new expiration date for the subject product registrations is now June 15, 2021.**

Please note that this product is still subject to all other previous required conditions of registration. If you have any questions, please contact Vanessa Emerson, at emerson.vanessa@epa.gov or 703.347.0360.

Sincerely,

Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



Sergeant's Pet Care Products, Inc.

10077 South 134th Street • Omaha, NE 68138 • Telephone 402.938.7000 • Fax 402.938.7099 • www.sergeants.com

March 15, 2019

Elizabeth Fertich, PM 4
Invertebrate & Vertebrate Branch I
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Subject: Two-Year Registration Extension for:

EPA Reg. No. 2517-178 6/15/19
Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs

EPA Reg. No. 2517-145
Sergeant's Fipronil + Etofenprox + Methoprene Spot On for Cats

EPA Reg. No. 2517-147
Sergeant's Fipronil + Etofenprox + Pyriproxyfen Spot On for Cats

EPA Reg. No. 2517-148
Sergeant's Fipronil + Etofenprox Spot On for Cats

Dear Ms. Fertich,

Sergeant's Pet Care Products, Inc. (EPA Company No. 2517) is hereby submitting Applications for registration time limit extension for additional two (2) years. This action is to comply with the conditions of registration for the subject line products.

Please find enclosed with this letter, EPA Application Forms 8570-1 for each registration.

The Applications are being submitted over 90 days prior to expiration as recommended by the Agency to avoid registration lapse. No changes have been made to the CSFs or Master Labels on file for these registrations. Should you have any questions regarding this submission, please contact me at 402-938-7065 or by email at prince.bamaze@perrigo.com.

Sincerely,

Prince M. Bamaze
Regulatory Affairs,
Sergeant's Pet Care Products, Inc., d.b.a.
Perrigo Animal Health

Enclosures

EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 2517-178		2. EPA Product Manager Elizabeth Fertich	
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
<input type="checkbox"/> Check if this is a new address			
Section II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated xx-xx-xx <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.)			
Application for 2-Year Registration Extension for EPA Reg. No. 2517-178			
Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
		5. Location of Label Directions <input type="checkbox"/> On Can <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Prince M. Bamaze		Title Regulatory Affairs	Telephone No. (Include Area Code) 402-938-7065
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			3. Date Application Received (Stamped)
2. Signature BY: <i>Prince M. Bamaze</i>		3. Title Regulatory Affairs Sergeant's Pet Care Products, Inc.	
4. Typed Name: Prince M. Bamaze		5. Date: 03/15/2019	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 14, 2019

Prince M. Bamaze
Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

Subject: Notification per PRN 98-10 – Addition of Alternate Brand Name
Product Name: SERGEANT'S IMIDACLOPRID + PERMETHRIN +
PYRIPROXYFEN SQUEEZE ON FOR DOGS
EPA Registration Number: 2517-178
Application Date: August 30, 2019
Decision Number: 555195

Dear Mr. Bamaze:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name: "ADVECTA ULTRA FOR DOGS" has been added to the product record.

If you have any questions, you may contact Elizabeth Fertich at 703-347-8560 or by email at fertich.elizabeth@epa.gov

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Fertich".

Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Emerson, Vanessa

From: Fertich, Elizabeth
Sent: Thursday, November 14, 2019 11:17 AM
To: Kelly Hoskins
Cc: IVB1; Aubuchon, Matthew; Emerson, Vanessa; Aubee, Catherine; Laws, Meredith; Eagle, Venus; Prince Bamaze
Subject: RE: 2517-178 ABN
Attachments: 2517-178 (555195)- ABN notification.pdf

Please see the revised letter. This supersedes the letter sent and dated 11/6/19.

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
fertich.elizabeth@epa.gov
703-347-8560

From: Kelly Hoskins <Kelly.Hoskins@petiq.com>
Sent: Tuesday, November 12, 2019 10:23 AM
To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>; Emerson, Vanessa <emerson.vanessa@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Prince Bamaze <Prince.Bamaze@petiq.com>
Subject: FW: 2517-178 ABN
Importance: High

Beth,
I am following up on my email from last week and looking to see if this issue can be approved and closed out.

Kelly Hoskins | Manager of Regulatory Affairs

P: (402) 938-7079
C: (402) 926-6787
A: 10077 S. 134th Street, Omaha, NE 68138
E: Kelly.Hoskins@petiq.com



PLEASE NOTE: I am now part of [PetIQ](https://www.petiq.com) and my email address has changed to kelly.hoskins@petiq.com. I will still receive forwarded email from my old Perrigo Animal Health email address, but only through December 31, 2019. Please make this address change in your contacts.

From: Kelly Hoskins
Sent: Thursday, November 7, 2019 8:34 AM
To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>; Emerson, Vanessa

<emerson.vanessa@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Laws, Meredith
<Laws.Meredith@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Prince Bamaze <Prince.Bamaze@petiq.com>

Subject: RE: 2517-178 ABN

Importance: High

Beth,
My apologies in not including both Dog and Cat approvals, I was not aware of the depth of review the EPA has now gone to in approving names by now looking not only at the chemicals involved but the percent's as well. Can the EPA provide the relevant law, regulation, etc. so we can use this going forward after our Legal has reviewed it?

As we can see below we are building a group of similar products using similar actives, and the Ultra is in line with that as an appropriate name and therefor there should be no reason not to approve the requested ABN.

APPROVED - Advecta Plus for Cats for EPA Reg No 2517-175	imidacloprid (9.1) pyriproxyfen (.46)
APPROVED - Advecta Plus for Dogs for EPA Reg No 2517-176	imidacloprid (9.1) pyriproxyfen (.46)
PENDING - Advecta Ultra for Dogs for EPA Reg No 2517-178 (44)	imidacloprid (8.8), pyriproxyfen (.44) and permethrin

Kelly Hoskins | Manager of Regulatory Affairs

P: (402) 938-7079

C: (402) 926-6787

A: 10077 S. 134th Street, Omaha, NE 68138

E: Kelly.Hoskins@petiq.com



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From: Fertich, Elizabeth <fertich.elizabeth@epa.gov>

Sent: Thursday, November 7, 2019 7:17 AM

To: Kelly Hoskins <Kelly.Hoskins@petiq.com>

Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>; Emerson, Vanessa <emerson.vanessa@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>; Eagle, Venus <Eagle.Venus@epa.gov>; Prince Bamaze <Prince.Bamaze@petiq.com>

Subject: RE: 2517-178 ABN

Kelly,
Venus and I discussed this at length and I aware of the history. We discussed the "Advecta" part of the issue with your proposed brand name this morning and I agree with the points you have made below. Flagging the use of "Advecta" in an ABN was due to an administrative error in our system and I apologize for the oversight. However, this does not resolve the issue with the word "ultra" as part of your ABN. As part of your discussions with Venus back in August, she flagged "Advecta Ultra" as an unacceptable name. This was because there was no other "Advecta" product that contained a lesser percentage of the same active ingredient used in the **same type of product**. "Advecta Plus" was determined to be appropriate for a cat product containing imidacloprid (9.1) and pyriproxyfen (.46). This does not confer to a dog product (2517-178) containing imidacloprid (8.8), pyriproxyfen (.44) and permethrin (44) (2517-178) being permitted to use "Advecta Ultra for Dogs" as an ABN.

Kind regards,
Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
fertich.elizabeth@epa.gov
703-347-8560

From: Kelly Hoskins <Kelly.Hoskins@petiq.com>
Sent: Wednesday, November 06, 2019 3:21 PM
To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>; Emerson, Vanessa <emerson.vanessa@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>; Prince Bamaze <Prince.Bamaze@petiq.com>
Subject: RE: 2517-178 ABN

Beth,
Thank you the update on this action. I do believe further discussion is in order on this request at it appears you may not have to complete history.

Yes we are aware of Venus's initial position on this name as we submitted multiple names to get a better understanding of what was acceptable and what was not. Upon further emails and discussion with both Venus and Meredith as well as discussions of PETIQ ownership of the Advecta trademark and company, subsidiary's (Sergeants) we were able to come to a resolution in regards using the Advecta name on one of our other products as we move the PetiQ owned brand names from their contractual company products to Sergeants as they now own us.

Attached you will find the acceptance letter of IVB3 approving the name Advecta Plus for Cats for EPA Reg No 2517-175, which is a two AI product.

Therefor our request dated 30 August 2019, attached, is both an Approved Brand on our company registrations as well as being a differentiated product in line with the existing established product.

We respectively request that this request be reconsidered at this time.

Kelly Hoskins | Manager of Regulatory Affairs

P: (402) 938-7079

C: (402) 926-6787

A: 10077 S. 134th Street, Omaha, NE 68138

E: Kelly.Hoskins@petiq.com



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From: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Sent: Wednesday, November 6, 2019 6:59 AM
To: Kelly Hoskins <Kelly.Hoskins@petiq.com>
Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>; Emerson, Vanessa <emerson.vanessa@epa.gov>
Subject: RE: 2517-178 ABN

Kelly,

As part of our ongoing efforts to maintain consistency across the IVB's, I followed up with Venus on this as we discussed a similar name for another Sergeant's product at one of our IVB PM meetings a few months ago. The name in question for Venus' team product was Advecta Ultra and it was flagged as unacceptable. Here's the text from the email she sent to you on 8/28/19.

- Advecta Ultra (What makes the product ultra? May be acceptable in the future if there was a previous Sergeant's Advecta product that contained for example a lesser percentage of the same active ingredient used in the same type of product. Then the claim of "ultra" would be true.)

Given the similarity of the name you are proposing for 2517-178, ADVECTA ULTRA FOR DOGS to the name discussed previously with IVB3, this name is also not acceptable at this time.

The name "Advecta" is also currently used by another company.

Vanessa will follow up with a letter indicating the ABN is not acceptable. I just wanted to provide the context for the decision.

Kind regards,
Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
fertich.elizabeth@epa.gov
703-347-8560

From: Kelly Hoskins <Kelly.Hoskins@petiq.com>
Sent: Monday, November 04, 2019 11:16 AM
To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>; Emerson, Vanessa <emerson.vanessa@epa.gov>
Subject: RE: 2517-178 ABN

Thank you Beth.

Kelly Hoskins | Manager of Regulatory Affairs
P: (402) 938-7079
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Sent: Monday, November 4, 2019 9:03 AM
To: Kelly Hoskins <Kelly.Hoskins@petiq.com>
Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>; Emerson, Vanessa <emerson.vanessa@epa.gov>
Subject: RE: 2517-178 ABN

Hi Kelly,
I'm working on it today.
Kind regards,
Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
fertich.elizabeth@epa.gov
703-347-8560

From: Kelly Hoskins <Kelly.Hoskins@petiq.com>
Sent: Friday, November 01, 2019 11:53 AM
To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>; Emerson, Vanessa <emerson.vanessa@epa.gov>
Subject: RE: 2517-178 ABN

Beth,
Just checking to see if you were able to complete this ABN request this week?

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From: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Sent: Monday, October 28, 2019 10:33 AM
To: Kelly Hoskins <Kelly.Hoskins@petiq.com>
Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>; Emerson, Vanessa <emerson.vanessa@epa.gov>
Subject: RE: 2517-178 ABN

Kelly,
I wanted to let you know that Vanessa submitted the action to me for final review. I have several PRIA actions to do ahead of this one, but will try and finish it by the end of the week.
Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
fertich.elizabeth@epa.gov
703 347-8560

From: Fertich, Elizabeth
Sent: Monday, October 28, 2019 11:25 AM
To: Kelly Hoskins <Kelly.Hoskins@petiq.com>
Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>; Emerson, Vanessa <emerson.vanessa@epa.gov>
Subject: RE: 2517-178 ABN

Kelly,
I received your voicemail for this product too. The only status update that I can provide is that the action is assigned to Vanessa Emerson and it is in her queue for review. We have a significant backlog of non-PRIA actions and are working through them in order of receipt.
Kind regards,
Beth

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US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
fertich.elizabeth@epa.gov
703-347-8560

From: Kelly Hoskins <Kelly.Hoskins@petiq.com>
Sent: Friday, October 25, 2019 10:47 AM
To: Fertich, Elizabeth <fertich.elizabeth@epa.gov>
Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>
Subject: 2517-178 ABN

Beth,
I was informed that this 2517-178 ABN action is sitting with you, can you provide an update on the status?

Kelly Hoskins | Manager of Regulatory Affairs

P: (402) 938-7079

C: (402) 926-6787

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 6, 2019

Prince M. Bamaze
Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138-3710

*Superseded by
11/14/2019 letter*

Subject: Notification per PRN 98-10 – Addition of Alternate Brand Name
Product Name: SERGEANT'S IMIDACLOPRID + PERMETHRIN +
PYRIPROXYFEN SQUEEZE ON FOR DOGS
EPA Registration Number: 2517-178
Application Date: August 30, 2019
Decision Number: 555195

Dear Mr. Bamaze:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the request is not acceptable for the following reasons:

1. The proposed alternate brand name, "ADVECTA ULTRA FOR DOGS", is similar to a previously submitted alternate brand name that was also unacceptable called "Advecta Ultra". It was deemed unacceptable because the word "ultra" is misleading.
2. The name "Advecta" is currently being used by another company.

No further processing of this application will occur. You may submit a new application addressing the deficiencies listed above for future consideration. Our records have been updated accordingly to note that this notification is unacceptable.

If you have any questions, you may contact Vanessa Emerson at 703-347-0360 or by email at emerson.vanessa@epa.gov.

Sincerely,

Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Emerson, Vanessa

From: Fertich, Elizabeth
Sent: Wednesday, November 6, 2019 7:59 AM
To: Kelly Hoskins
Cc: IVB1; Aubuchon, Matthew; Emerson, Vanessa
Subject: RE: 2517-178 ABN

Kelly,
As part of our ongoing efforts to maintain consistency across the IVB's, I followed up with Venus on this as we discussed a similar name for another Sergeant's product at one of our IVB PM meetings a few months ago. The name in question for Venus' team product was Advecta Ultra and it was flagged as unacceptable. Here's the text from the email she sent to you on 8/28/19.

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Subject: RE: 2517-178 ABN

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Subject: RE: 2517-178 ABN

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Office of Pesticide Programs
Registration Division (7505P)
Invertebrate and Vertebrate Branch 1 (IVB1)
Product Manager 4
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Subject: RE: 2517-178 ABN

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Office of Pesticide Programs
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Cc: IVB1 <IVB1@epa.gov>; Aubuchon, Matthew <Aubuchon.Matthew@epa.gov>

Subject: 2517-178 ABN

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Kelly Hoskins | Manager of Regulatory Affairs

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August 30, 2019

Jacquelyn Herrick, PM 3
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Subject: **Notification for Alternate Brand Names per PR Notice 98-10.**

Dear Ms. Herrick,

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is hereby submitting applications for notification, to add alternate brand names to the EPA Registration Numbers listed below. In support of this action, please find enclosed an Application (EPA Form 8570-1) for each EPA Registration Number listed:

- **EPA Reg. No. 2517-134, Sergeant's Fipronil + Methoprene Squeeze-On for Dogs**
Proposed Alternate Brand Name: ***PetAction Pro for Dogs***
- **EPA Reg. No. 2517-135, Sergeant's Fipronil + Methoprene Spot-On for Cats**
Proposed Alternate Brand Name: ***PetAction Pro for Cats***
- **EPA Reg. No. 2517-178, Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs**
Proposed Alternate Brand Name: ***Advecta Ultra for Dogs***

This Notification is consistent with provisions of PR Notice 98-10 and EPA regulations at 40 CRF 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C Sec. 1001 to willfully make a false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CRF 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Should you have any questions regarding this submission, please contact me at 402-938-7065 or by email at prince.bamaze@Petiq.com

Sincerely,



Prince M. Bamaze

Regulatory Affairs,
Sergeant's Pet Care Products, Inc.
A PetIQ, Inc. Company

Enclosures

EPA
 United States
Environmental Protection Agency
 Washington, DC 20460

☐ **Registration**
☐ **Amendment**
☒ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2517-178	2. EPA Product Manager Jacquelyn Herrick	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs	PM # 3	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX
<input type="checkbox"/> Submission in response to Agency letter dated XX-XX-XX	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification for Alternate Brand Names per PR notice 98-10. Please see cover letter for details.**Section III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
*Certification must be submitted		If "Yes" Unit Packaging wgt. 0.014 fl oz (0.4 ml) 0.034 fl oz (1.0 ml) 0.085 fl oz (2.5 ml) 0.135 fl oz (4.0 ml)	No. per Container 1,2,3,4,5,6, 12,24,50,75 100 vials	If "Yes" Package wgt.	No. per Container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Prince M. Bamaze	Title Regulatory Affairs	Telephone No. (Include Area Code) 402 938-7065
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped)
2. Signature BY: <i>Prince M. Bamaze</i>	3. Title Regulatory Affairs, Sergeant's pet Care Products, Inc.	
4. Typed Name: Prince M. Bamaze	5. Date: 08/30/2019	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 21, 2019

Prince Bamaze
Regulatory Affairs
Sergeant's Pet Care Products, Inc.
10077 South 134th Street
Omaha, NE 68138

Subject: Condition of Registration –Storage Stability and Corrosion Characteristics Data
Product Name: Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On
for Dogs
EPA Registration Number: 2517-178
Application Date: July 12, 2018
Decision Number: 543055

Dear Mr. Bamaze:

The Agency has reviewed the study submitted to fulfill the conditional data requirement referred to above, in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the review is enclosed. The study has been classified as acceptable. The condition of registration is considered fulfilled.

If you have any questions, please contact Letu Kassa by phone at 703-347-0462, or via email at kassa.letu@epa.gov.

Sincerely,

A handwritten signature in black ink, which appears to read "Elizabeth Fertich".

Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: October 3, 2018

SUBJECT: STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS
(830.6320) REVIEW

ACCELERATED STUDY ☐; ONE YEAR STUDY ☒;
OVER 1 YEAR STUDY ☐

MP ☐ EP ☒ EUP ☐

DP BARCODE No.: 448331 REG. No.: 2517-178

DECISION No.: 543055 MRID No(s): 506297-01

PRODUCT NAME: Sergeant's Imidacloprid + Permethrin + Pyriproxyfen

COMPANY: Sergeant's Pet Care Products, Inc.

FROM: Linda Mascall / Bruce Kitchens
Product Chemistry Team

Chemistry, Inerts and Toxicology Assessment Branch (CITAB)/RD (7505P)

TO: Letu Kassa / Elizabeth Fertich, RM 04
Invertebrate and Vertebrate Branch 1 / RD (7505P)

I. CONCLUSIONS:

STORAGE STABILITY (830.6317):

☒ ACCEPTABLE

☐ UNACCEPTABLE*

☐ UPGRADEABLE*

40CFR158.190 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

CORROSION CHARACTERISTICS (830.6320):

☒ ACCEPTABLE

☐ UNACCEPTABLE*

☐ UPGRADEABLE*

40CFR158.190 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

* If unacceptable or upgradeable describe the deficiency and provide recommendations

Comments & Recommendations:

The Imidacloprid, Pyriproxyfen and Permethrin active ingredients in Sergeant's 0.40mL Squeeze-On ampoules remained within specification after 12 months of storage at ambient temperature.

The formulation showed no signs of interaction with the packaging during this storage study. The TekniPlex ampoules made with pharmaceutical grade cyclic olefin co-polymer film are suitable for storage of this product.

II. STUDY SUMMARY

A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

☒ Yes

☐ No

B. PRODUCT INFORMATION

Active ingredient(s): Imidacloprid, Pyriproxyfen and Permethrin

Label claim(s) Nominal concentration(s) (%): 8.80; 44.00; 0.44

Initial concentration(s) of the AI(s) (%) used in the study: 8.65; 44.9; 0.435

Lower certified limits (%) based on AI % on the label: 8.36; 42.68; 0.396

Lower certified limits (%) based on AI % in the study: 8.2175; 43.553; 0.3915

C. EXPERIMENTAL PARAMETERS

Temperature: ☐ Freezer; Room ☐; Warehouse ☒; 54°C ☐; Other ☐

Humidity: Indicate 25°C / 50% (if provided)

Duration of study: ☒ 2 weeks; ☒ 1 year; ☐ over 1 year

Type of container: ☐ Glass; ☐ Metal; ☒ HDPE; ☐ Fluorinated HDPE; ☐ Other

Analysis at intervals: ☒ 0 (initial);

☒ 3 months; ☒ 6 months

☒ 9 months; ☒ 12 months

☐ Over 12 months

D. ANALYTICAL METHOD

Method	DETECTOR
Gas chromatography (GC)	<input type="checkbox"/> FID (Flame Ionization Detector) <input type="checkbox"/> ECD (Electron Capture Detector) <input type="checkbox"/> N/P (Nitrogen/Phosphorous Detector) <input type="checkbox"/> Other
Capillary Gas chromatography (CGC)	<input type="checkbox"/> FID (Flame Ionization Detector) <input type="checkbox"/> ECD (Electron Capture Detector) <input type="checkbox"/> N/P (Nitrogen/Phosphorous Detector) <input type="checkbox"/> Other
High Pressure Liquid chromatography (HPLC)	<input checked="" type="checkbox"/> UV/VIS (nm) <input type="checkbox"/> RI (Refractive Index) <input type="checkbox"/> Other
GC-MS / LC-MS	Specify
Other	Specify

E. RESULTS

Active Ingredient	Initial	2 Weeks 54°C	3 Month R.T.	6 Month R.T.	9 Month R.T.	12 Month R.T.
Imidacioprid	8.65	8.68	8.76	8.69	8.84	8.69
Pyriproxyfen	0.435	0.429	0.427	0.435	0.441	0.423
Total Permethrin	44.9	44.9	45.4	44.6	43.2	43.6

PROCESSING REQUEST

Reg No: 2517-178

Decision #548512

Description: CSF Notification

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated: Alternate CSF 1 dated 2/1/2019

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Jen Gaines

Division: RD

Phone: 305-5967

Date: 8/1/2019



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 1, 2019

Prince Bamaze
Regulatory Affairs
Sergeant's Pet Care Products, Inc.
dba Perrigo Animal Health
10077 South 134th St
Omaha, NE 68138

Subject: CSF Notification per PRN 98-10 – Adding alternate suppliers of active and inert ingredients.
Product Name: Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze on for Dogs
EPA Registration Number: 2517-178
Application Date: February 1, 2019
Decision Number: 548512

Dear Mr. Bamaze:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 02/01/2019

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink, which appears to read "Jennifer Gaines", followed by a small mark that looks like a stylized "m" or a flourish.

Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

February 01, 2019

Venus Eagle, PM 1
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Pesticide Notification per PR Notice 98-10 for:

EPA Registration No. 2517-178

Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs

EPA Registration No. 2517-176

Sergeant's Imidacloprid + Pyriproxyfen Squeeze On for Dogs

EPA Registration No. 2517-175

Sergeant's Imidacloprid + Pyriproxyfen Spot On for Cats

EPA Registration No. 2517-174

Sergeant's 9.1% Imidacloprid Squeeze On for Dogs

EPA Registration No. 2517-173

Sergeant's 9.1% Imidacloprid Spot On for Cats

Dear Ms. Eagle,

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is hereby submitting Pesticide Notification, to add Alternate Suppliers of active and inert ingredients to Basic CSFs, for EPA Registration Numbers **2517-178, 2517-176, 2517-175, 2517-174** and **2517-173**. The enclosed CSFs supersedes all current and/or pending CSFs for these registrations.

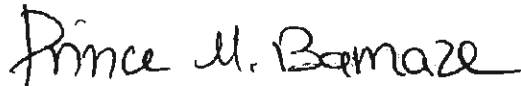
Please find enclosed, in support of the action for each registration:

- Application for Pesticide Notification (EPA Form 8570-1);
- Copy of Formulator's Exemption (EPA Form 8570-27);
- Copy of updated Basic CSF (EPA Forms 8570-4), dated February 01, 2019.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Should you have any questions regarding this submission, please contact me at 402-938-7065 or by email at prince.bamaze@perrigo.com.

2019-02-01 10:17:33

Sincerely,

A handwritten signature in black ink that reads "Prince M. Bamaze". The signature is written in a cursive, flowing style.

Prince M. Bamaze

Regulatory Affairs,

Sergeant's Pet Care Products, Inc., d.b.a.

Perrigo Animal Health

Enclosures

United States Environmental Protection Agency Washington, DC 20460 Formulator's Exemption Statement <i>(40 CFR 152.85)</i>								
Applicant's Name and Address Sergeant's Pet Care Products, Inc. 10077 South 134 th Street Omaha, NE 68138	EPA File Symbol/Registration Number 2517-178 Product Name <i>Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs</i> Date of Confidential Statement of Formula (EPA Form 8570-4) February 01, 2019							
As an authorized representative of the applicant for registration of the product identified above, I certify that:								
(1) This product contains the following active ingredient(s): Permethrin, Imidacloprid, Pyriproxyfen								
(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.								
(3) Indicate by checking (A) or (B) below which paragraph applies:								
<input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1)								
OR								
<input type="checkbox"/> (B) The Confidential Statement of Formula (CSF) (EPA Form 8750-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF								
(4) The following active ingredients in this product qualify for the formulator's exemption								
Source								
Active Ingredient	Product Name	Registration Number						
Imidacloprid Imidacloprid Imidacloprid Pyriproxyfen Pyriproxyfen Pyriproxyfen Pyriproxyfen Permethrin Permethrin Permethrin Permethrin								
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Signature</td> <td style="width: 33%;">Name and Title</td> <td style="width: 33%;">Date</td> </tr> <tr> <td> </td> <td> Prince M. Bamaze, Regulatory Affairs </td> <td> February 01, 2019 </td> </tr> </table>			Signature	Name and Title	Date		Prince M. Bamaze, Regulatory Affairs	February 01, 2019
Signature	Name and Title	Date						
	Prince M. Bamaze, Regulatory Affairs	February 01, 2019						

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy
Yellow - Applicant copy

EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 2517-178		2. EPA Product Manager Venus Eagle	
4. Company/Product (Name) Sergeant's Pet Care Products, Inc. / Sergeant's Imidacloprid + Permethrin + Pyriproxyfen Squeeze On for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138-3710 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Submission in response to Agency letter dated XX-XX-XX <input checked="" type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification per PR notice 98-10 of Alternate Suppliers for Active and Inert Ingredients.			
Section III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.014 fl oz (0.4 ml) 0.034 fl oz (1.0 ml) 0.085 fl oz (2.5 ml) 0.135 fl oz (4.0 ml)	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per Container 1,2,3,4,5,6, 12,24,50,75 100 vials	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Single Collar	
5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
Section IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Prince M. Bamaze		Title Regulatory Affairs	
		Telephone No. (Include Area Code) 402 938-7065	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature BY: <i>Prince M. Bamaze</i>		3. Title Regulatory Affairs, Sergeant's pet Care Products, Inc.	
4. Typed Name: Prince M. Bamaze		5. Date: 02/01/2019	